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QP3744

Practitioner's Docket No. 1981-1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of _____
Inventor(s)

for _____
Title of invention

the specification of which is being transmitted herewith

OR

In re application of: CASALE, Guillermo Arturo

Application No.: 10 / 586,755

Group No.: 3744

Filed: 08-24-2006

Examiner:

For: SYSTEM FOR CONTROL, VERIFICATION AND RECORDING OF THE PERFORMANCE
OF A RADIOISOTOPE GENERATOR'S OPERATIONS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is mandatory;
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to Commissioner for Patents, P.O.
Box 1450, Alexandria, VA 22313-1450

37 C.F.R. § 1.8(a)

37 C.F.R. § 1.10 *

☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"

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TRANSMISSION

☐ facsimile transmitted to the Patent and Trademark Office, (571) 273-8300.

FEB 19 2007

Date: _____

Signature _____

(type or print name of person certifying)

* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

- (1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- (3) Before the mailing date of a first Office action on the merits; or
- (4) Before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114."

37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

"A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability." 37 C.F.R. § 1.56(b)

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. § 1.51(d).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections
and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications

6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ EPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☒ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met, the examiner has an obligation to consider the information."
Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability (37 C.F.R. § 1.97(h)), or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)

NOTE: With respect to the list required by paragraph (b) of 37 C.F.R. § 1.98, the Notice of April 20, 1992 (1138 O.G. 37-41) points out that:

"The list may not be incorporated into the specification but must be submitted in a separate paper. A separate list is required so that it is easy to confirm that applicant intends to submit an information disclosure statement, and because it provides a readily available checklist for the examiner to indicate which identified documents have been considered. A copy of a separate list will also provide a simple means of communication to applicant to indicate the listed documents that have been considered and those listed documents that have not been considered. Use of form PTO-1449, "Information Disclosure Citation, is encouraged."

See also § 609, M.P.E.P., 8th Edition.

NOTE: "An information disclosure statement may include two list[s] (and two certifications)) . . . in situations where some of the information listed was cited in a communication from a foreign patent office not more than three months prior to filing the statement and some was not, but was not known more than three months prior to filing the statement." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

See also § 609, M.P.E.P., 8th Edition.

NOTE: With respect to the examiner's consideration of the Information Disclosure Statement, the Notice of April 20, 1992 (1138 O.G. 37-41) states:

*"If information is listed in the specification rather than in a separate paper, or if the other content requirements *** are not complied with, the examiner will notify applicant in the next Office action that the information has not been considered. It should be noted, however, that no copy of a U.S. patent application is required to be submitted. ***"*

"Examiners must consider all citations submitted in conformance with the rules and this section and place their initials adjacent [sic] the citations on a list or in the boxes provided on a form PTO-1449. If the citations are submitted on a list other than a form PTO-1449, the examiner may write "all considered" and his or her initials to indicate that all citations have been considered. If any of the citations are considered, a copy of the submitted list or form, as reviewed by the examiner, will be returned to the applicant with the next communication. The original copy of the form will be entered into the application file. The copy returned to applicant will serve both as acknowledgement of receipt of the information disclosure statement and as an indication that the references were considered by the examiner. Forms PTO-326 and PTOL-37 include a box to indicate the attachment of form PTO-1449.

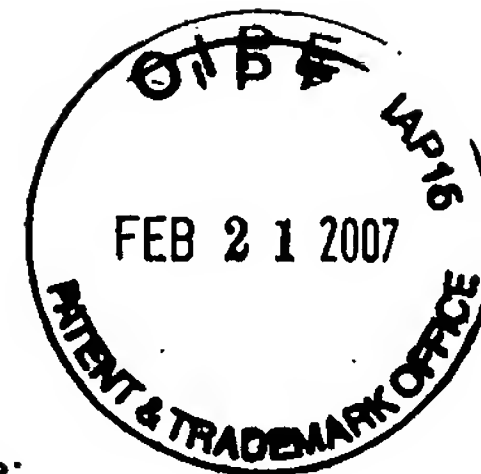
*"Information which complies with requirements as discussed in this section but which is in a non-English language will be considered in view of the concise explanation submitted *** and insofar as it is understood on its face, e.g., drawings, chemical formulas, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches. The examiner need not have the information translated unless it appears to be necessary to do so. *** The examiner should not require that a translation be filed by applicant. The examiner should not make any comment such as that the non-English language information has only been considered to the extent understood, since this fact is inherent.*

"Since information is required to be listed in a separate paper rather than in the specification, there is no need to mark "All checked" or "Checked" in the margin of a specification containing citations.

"If a statement fails to comply with the requirements as discussed in this section for an item of information, a line should be drawn through the citation to show that it has not been considered. The other items of information listed that do comply with the rules and this section will be considered by the examiner and will be appropriately initialed.

* * * * *

"A citation listed on form PTO-1449 and considered by the examiner in accordance with this section will be printed on the patent. A citation listed in a separate paper, equivalent to but not on form PTO-1449, and considered by the examiner in accordance with this section will be printed on the patent if the list is on a separate sheet which is clearly identified as an information disclosure statement and the list lends itself to easy capture of the necessary information by the Office printing contractor, i.e., each item of information is listed on a single line, the lines are at least double-spaced from each other, the information is uniform in format for each listed item, the list includes a column for the examiner's initials to indicate that the information was considered. If a citation is not printed on the patent but has been considered by the examiner in accordance with this section, the patented file will reflect that fact . . . "



Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. § 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include:
"A legible copy of:

- (i) Each U.S. patent application publication and U.S. and foreign patent;
- (ii) Each publication or that portion which caused it to be listed;
- (iii) For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and
- (iv) All other information or that portion which caused it to be listed; . . ."

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

- ☐ Exception(s) to above:
 - ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
 - ☐ Cumulative patents or publications identified in Section 5.

Section 9. Concise Explanation of English Language Listed Information Items (OPTIONAL)

NOTE: "Applicants may, if they wish, provide a concise explanation of why English-language information is being submitted and how it is understood to be relevant. Concise explanations are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more are highly relevant to patentability." Notice of April 20, 1992 (1138 O.G. 37-41, 38). See also § 609, M.P.E.P., 8th Edition.

United States Patent No. 5,774,782, issued June 30, 1998 to Mirzadeh, et al., discloses a .sup.99 Mo/.sup.99m Tc generator system including a sorbent column loaded with a composition containing .sup.99 Mo. The sorbent column has an effluent end in fluid communication with an anion-exchange column for concentrating .sup.99m Tc eluted from the sorbent column. A method of preparing a concentrated solution of .sup.99m Tc includes the general steps of: a. providing a sorbent column loaded with a composition containing .sup.99 Mo, the sorbent column having an effluent end in fluid communication with an anion-exchange column; b. eluting the sorbent column with a salt solution to elute .sup.99m Tc from the sorbent and to trap and concentrate the eluted .sup.99m Tc on the ion-exchange column; and c. eluting the concentrated .sup.99m Tc from the ion-exchange column with a solution comprising a reductive complexing agent.

United States Patent No. 4,782,231, issued November 1, 1988 to Svoboda, et al., discloses a standard component .sup.99m TC elution generator useful for medical purposes and consisting of prefabricated component parts. The main generator column of the device may be used both as an irradiation container and an elution container, enabling the user to supply activated or no activated parts. The main generator column made from by neutrons little activable materials serves first as reactor irradiation ampoule and after having been activated in the reactor by neutrons and after a simple adjustment serves directly as the generator column. It is filled with

water insoluble molybdates or polymolybdates (with the molybdenum content in the range 10-40%), easily releasing ^{99m}Tc generated by radioactive decay of the mother ^{99}Mo formed in it by neutron activation. This column filling serves originally as target material for reactor irradiations and afterwards it is directly used as the generator elution matrix.

United States Patent No. 4,837,110 issued June 6, 1989 to Kuhlmann, et al., discloses a technetium-99m generator, its preparation and its use wherein silica gels modified with amino groups or magnesium silicates are suitable carrier materials for technetium-99m generators since they retain copper(II) ions well and thus produce a copper-free elute.

United States Patent No. 4,280,053 issued July 21, 1981 to Evans, et al., describes a Technetium-99m generator has a matrix having a compound of molybdenum-99 bound into or forming the matrix, the compound of the molybdenum-99 being substantially insoluble in an eluant which can be used in a radiopharmaceutical and the molybdenum compound permitting diffusion of technetium-99m therethrough and elution therefrom. The molybdenum compound can be a monomolybdate, an isopolymolybdate or a heteropolymolybdate and zirconium molybdate is preferred although other cation molybdates may be used. Methods of preparation of the generator include dissolving irradiated molybdenum trioxide in alkaline solution and precipitating the molybdate at a selected pH and packing the precipitate in finely divided form into a column.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

- (c) ☐ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))
☐ in the practitioner's file.



SIGNATURE OF PRACTITIONER

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(type or print name of practitioner)

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